2.0 GENERAL INFORMATION

2.1 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K042303

2.1.1 Submitter Name, Address, Contact

Ortho-Clinical Diagnostics, Inc.
100 Indigo Creek Drive
Rochester, New York 14626-5101
(585) 453-3154

Contact Person: Sarah Glover

2.1.2 Preparation Date

Date 510(k) Summary Prepared: August 24, 2004

2.1.3 Device Name

Trade or Proprietary Name: VITROS Immunodiagnostic Products Anti-HBs Controls

Common Name: Anti-HBs Controls

Classification Name: 21CFR 862.1660 Quality Control Material (Assayed and Unassayed).

2.1.4 Predicate Device

The VITROS Immunodiagnostic Products Anti-HBs Controls are substantially equivalent to the current VITROS Immunodiagnostic Products Anti-HBs Controls (K003112).

2.1.5 Device Description

The VITROS Immunodiagnostic Products Anti-HBs Controls are comprised of three levels of controls in separate vials:

Control 1 (Negative)

Anti-HBs negative plasma obtained from donors who were tested individually and found to be negative for hepatitis B surface antigen, and for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (enzyme immunoassays, EIA).

Control 2 (Positive)

Anti-HBs negative plasma spiked with anti-HBs positive plasma to give a nominal VITROS Anti-HBs result of 25.00 mIU/mL. The positive plasma was obtained from donors who were tested individually and found to be negative for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (EIA).

Control 3 (Positive)

Anti-HBs negative plasma spiked with anti-HBs positive plasma to give a nominal VITROS Anti-HBs result of 380 mIU/mL. The positive plasma was obtained from donors who were tested individually and found to be negative for antibodies to human immunodeficiency virus (HIV 1+2) and hepatitis C virus (HCV) using FDA approved methods (EIA).

All controls contain antimicrobial agent and are freeze-dried.

The controls are assigned values from a minimum of 10 assays. The standard deviation is that which would be anticipated for single determinations of each control in a number of different laboratories using different reagent batches.

2.1.6 Device Intended Use

The VITROS Immunodiagnostic Products Anti-HBs Controls are intended for use in monitoring the performance of the VITROS Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Quantitative Reagent Pack on the VITROS Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.

2.1.7 Comparison to Predicate Device

The VITROS Immunodiagnostic Products Anti-HBs Controls are substantially equivalent to the current VITROS Immunodiagnostic Products Anti-HBs Controls (K003112).

Table 1 lists the characteristics of the VITROS Immunodiagnostic Products Anti-HBs Controls (new device) and the current VITROS Immunodiagnostic Products Anti-HBs Controls (predicate device).

Table 1. Comparison of New Device and Predicate Device

Device Characteristic	VITROS Immunodiagnostic Products Anti-HBs Controls (New device)	VITROS Immunodiagnostic Products Anti-HBs Controls (Predicate device)
Intended use	For use in monitoring the performance of the VITROS Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Quantitative Reagent Pack on the VITROS Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.	For use in monitoring the performance of the VITROS Immunodiagnostic System when used for the qualitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Reagent Pack on the VITROS ECi Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.
Matrix of controls	Human serum with added constituents of human origin and antimicrobial agents	Human serum with added constituents of human origin and antimicrobial agents
Control level	2 Positive and 1 negative	1 Positive and 1 negative
Expected values	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent lots. Values are lot specific.	Each control has a quoted mean value derived from a minimum of 10 assays and a standard deviation anticipated for single determinations of each control in a number of different laboratories using different reagent lots. Values are lot specific

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 27 2004

Ms. Sarah Glover
Regulatory Affairs Associate
Ortho-Clinical Diagnostics
100 Indigo Creek Drive
Rochester, NY 14626

Re: k042303
Trade/Device Name: VITROS Immunodiagnostic Products Anti-HBs Controls
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: August 24, 2004
Received: August 25, 2004

Dear Ms. Glover:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

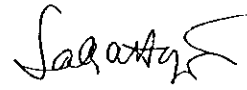
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2.2 Indications for Use Statement

510(k) Number (if known): K042303

Device Name: VITROS Immunodiagnostic Products Anti-HBs Controls

Indications for Use: The VITROS Immunodiagnostic Products Anti-HBs Controls are intended for use in monitoring the performance of the VITROS Immunodiagnostic System when used for the quantitative *in vitro* determination of total antibody to Hepatitis B surface antigen (anti-HBs) in human serum when using the VITROS Immunodiagnostic Products Anti-HBs Quantitative Reagent Pack on the VITROS Immunodiagnostic System. The performance of the VITROS Immunodiagnostic Products Anti-HBs Controls has not been established with any other anti-HBs assays.

For *in vitro* diagnostic use.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K042303

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)